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P O Box 1450 Alexandria, Virgima 22313-1450 www.uspto.gov

## NOTICE OF ALLOWANCE AND FEE(S) DUE

26161 7590 04/14/2009

FISH & RICHARDSON PC P.O. BOX 1022

P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022 EXAMINER HAMUD, FOZIA M

ART UNIT PAPER NUMBER

1647 DATE MAILED: 04/14/2009

 APPLICATION NO.
 FILING DATE
 FIRST NAMED INVENTOR
 ATTORNICY DOCKET NO.
 CONFRMATION NO.

 107-49,699
 12/30/2003
 Terry B. Strom
 13985-057002
 9466

TITLE OF INVENTION; MODULATION OF IL-2- AND IL-15-MEDIATED T CELL RESPONSES

 APPLN. TYPE
 SMALL ENTITY
 ISSUE FEE DUT
 PUBLICATION FEE DUT
 PREV. PAID ISSUE FEE
 TOTAL FEES) DUT
 DATE DUT

 nonprovisional
 NO
 \$1510
 \$300
 \$0
 \$1810
 07/14/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THE APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

# Complete and send this form, together with applicable fee(s), to: Mail Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where

appropriate. All further indicated unless correct maintenance fee notifica	ed below or directed otl	ng the Patent, advance on herwise in Block 1, by (	rders and notification a) specifying a new co	of ma	aintenance fees wondence address;	ill be and/o	mailed to the current r (b) indicating a sepa	corre trate "	spondence address as FEE ADDRESS" for	
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block I for any change of address)					Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers, Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.					
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									(Depositor's name)	
				_					(Signature)	
									(Date)	
APPLICATION NO.	FILING DATE		FIRST NAMED INVEN	TOR		ATTO	RNEY DOCKET NO.	CO	NFIRMATION NO.	
10/749,699 TITLE OF INVENTION	12/30/2003 i: MODULATION OF II	-2- AND IL-15-MEDIA	Terry B. Strom ATED T CELL RESP	ONSI	ES		13985-057002		9466	
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE D	UE	PREV. PAID ISSU	FEE	TOTAL FEE(S) DUE		DATE DUE	
nonprovisional	NO	\$1510	\$300		\$0		\$1810		07/14/2009	
EXAM	TINER	ART UNIT	CLASS-SUBCLASS		1					
HAMUD,	FOZIA M	I647	530-351000	_	_					
"Fee Address" ind PTO/SB/47; Rev 03- Number is required.  3. ASSIGNEE NAME A	condence address (or Cha B/122) attached. lication (or "Fee Address 32 or more recent) attack LND RESIDENCE DATA	inge of Correspondence		ip to inative single or ag attori Il be p	3 registered patently, firm (having as a gent) and the namelys or agents. If rinted,	memb es of u no nan	p to a 2		ent has been filed for	
(A) NAME OF ASSI	GNEE riate assignee category or	categories (will not be p	(B) RESIDENCE: (C	TTY:	and STATE OR C	OUNT	(RY)	oup en	ntity Government	
☐ Issue Fee ☐ Publication Fee (No small entity discount permitted) ☐ Advance Order - # of Copies			A check is enclosed.  Payment by credit card. Form PTO-2038 is attached.  The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number (enclose an extra copy of this form).							
	ns SMALL ENTITY state	as. See 37 CFR 1.27.					ΓΙΤΥ status. Sec 37 Cl			
interest as shown by the	ia Publication Fee (if req records of the United Sta	uired) will not be accepte tes Patent and Trademark	ca from anyone other the k Office.	nan th	e applicant; a regi	stered.	attorney or agent; or th	ne assi	gnee or other party in	
Authorized Signature			Date							
Typed or printed name			Registration No.							
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PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.



## UNITED STATES PATENT AND TRADEMARK OFFICE

#### UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS

P O Box 1450 Alexandra, Virgima 22313-1450 www.uspto.gov

DATE MAILED: 04/14/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/749,699	12/30/2003	Terry B. Strom	13985-057002	9466		
26161 7.	590 04/14/2009	EXAMINER				
FISH & RICHAL	RDSON PC	HAMUD, FOZIA M				
P.O. BOX 1022		ART UNIT	PAPER NUMBER			
MINNEAPOLIS,	MN 55440-1022	1647				

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 135 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 135 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

## Notice of Allowability

Application No.	Applicant(s)	1
10/749,699	STROM ET AL.	
Examiner	Art Unit	٦
EOZIA M. HAMLID	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable. PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

- This communication is responsive to the amendment of 12/22/2008.
- 2. X The allowed claim(s) is/are 1, 35, 36, 43, 44, 45, 47, 48, 50 and 51, (now renumbered 1-10, respectively)...
- 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  $\square$  All b) ☐ Some\* c) ☐ None of the:
    - 1. T Certified copies of the priority documents have been received.
    - 2. Certified copies of the priority documents have been received in Application No.
    - 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

- 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
- CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) hereto or 2) to Paper No./Mail Date
  - (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. 

DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

- 1. | Notice of References Cited (PTO-892)
- 2. Notice of Draftperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statements (PTO/SB/08).
- Paper No./Mail Date
- 4. T Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 5. Notice of Informal Patent Application
- Interview Summary (PTO-413), Paper No./Mail Date
- 7. 

  Examiner's Amendment/Comment
- 8. X Examiner's Statement of Reasons for Allowance
- 9. ☐ Other

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Art Unit: 1647

#### DETAILED ACTION

## Response to Applicant's Amendment:

Applicants' amendment filed on 22 December 2008 has been entered.

#### Status of Claims:

2. Claims 2-34, 37-42, 46 and 49 have been cancelled. Claims 1, 35, 36, 43, 44, 45,

47, 48, 50 and 51, (now renumbered 1-10, respectively).

#### Oath/Declaration

 The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the citizenship of each inventor.

## REASONS FOR ALLOWANCE:

The rejection of claims 1, 35-36, 43-45, 47-48 and 50-51 made under 35
 U.S.C. 103(a) as being unpatentable Kim et al (The Journal of Immunology, 1998. Vol. 160, pages 5742-5748) in view of Strom et al (Transplantation Proceedings, 1995. Vol. 27. No.5. pages 18-20), is withdrawn.

The instant specification demonstrates that a combination of IL-2/Fc, mutlL-15/Fc and rapamycin prevents graft rejection and was unexpectedly more effective than any of

Application/Control Number: 10/749,699

Art Unit: 1647

the agents alone, see figures 11 and 12). Thus, the instant specification shows that the claimed combination achieves unexpected results relative to any of the agents alone.

### Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FOZIA M. HAMUD whose telephone number is (571)272-0884. The examiner can normally be reached on Monday-Friday: 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia Hamud Patent Examiner Art Unit 1647 09 April 2009

> /Bridget E Bunner/ Primary Examiner, Art Unit 1647